[redacted]

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ALILIFE TECHNOLOGICAL CO., LTD.
No. 77 Gongye Rd., Dali City Taichung County 412, Taiwan, ROC
Tel: 886-4-2492-6288 Fax: 886-4-2491-4401
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ALILIFE

# " 510(k) SUMMARY "

Submitter's Name: ***ALILIFE Technological Co., Ltd.***

*NO. 77. Gongye Rd. Dalli city Taichung county 412, Taiwan, R.O.C.*

Date summary prepared: August 23, 2005

Device Name:

| | |
|---|---|
| Proprietary Name: | ALILIFE Stand Up Powered Wheelchair, HC-300 |
| Common or Usual Name: | Standing Wheelchair |
| Classification Name: | Wheelchair, Standup, Class II, 21 CFR 890.3900 |

Indications for Use:

*The device is a product which change people position not only from sitting to standing and standing to sitting but also reclines and lifts the seat and back position. The product provides indoor and outdoor mobility.*

Description of the device:

*The ALILIFE Stand Up Powered Wheelchair, HC-300 is an indoor / outdoor Powered Wheelchair that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.*

Performance Testing:

*EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995. IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)*

Legally marketed device for substantial equivalence comparison:

*COMFORT Standing Wheelchair HERO 1 (K031621)*

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**Summary for substantial equivalence comparison:**

Mainframes materials of the two devices all meet the strength and fatigue tests and they are similar for the material aspects. The overall dimensions are similar. The two devices used the same type of armrest. Back upholstery material is also the same fabric. The electronic control systems between the two devices are same, Penny and Giles. Besides, the two devices use the same supplier for battery and recharge which are all passed by the UL certificated.

**The major differences existing are the overall dimension, the size of tires, and the weight limit is differences between the two devices.** The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2005

Dr. Ke-Min Jen
Official Correspondent
Alilife Technological Co., Ltd.
No. 58 Fu-Chiun Street
Hsin Chu City, Taiwan 30067
China

Re: K052375
Trade/Device Name: ALILIFE Stand Up Powered Wheelchair, HC-300
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: II
Product Code: IPL
Dated: August 23, 2005
Received: August 30, 2005

Dear Dr. Jen :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson for
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510 (K) Number ( If Known ): K052375

Device Name: *ALILIFE Stand Up Powered Wheelchair, HC-300*

Indications for Use:

***The device is a product which changes people position not only from sitting to standing and standing to sitting but also reclines and lifts the seat and back position. The product provides indoor and outdoor mobility.***

Target Population:

*For all individuals who need a standing Wheelchair with the possibility to change positions and who can not stand on their feet themselves such as people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc..*

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R. Ogden for MNM Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K052375